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10/535,608	01/06/2006	Hasan Kulaksiz	26605.00001	7597

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EXAMINER	
COUNTS, GARY W	
ART UNIT	PAPER NUMBER
1641	
MAIL DATE	DELIVERY MODE
12/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,608	KULAKSIZ ET AL.	
	Examiner	Art Unit	
	GARY W. COUNTS	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *2,5-14,17-21,23 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 4, 15, 16, 22 and 25-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 April 2008* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/26/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the species hemochromatosis in the reply filed on August 29, 2008 is acknowledged. The traversal is on the ground(s) that since the Examiner has noted that the diagnosis of hereditary hemochromatosis is enabled, it follows that detection of decreased amount of hepcidin compared to normal range, is also inherently enabled. By the same logic, the Exmainer has noted that diagnosis of chronic renal insufficiency is enabled. Applicant states that the detection of increased amount of hepcidin is also inherently enabled. Applicant further argues that without the requested election, no undue burden would be imposed upon the Examiner.

2. This is not found persuasive because applicant's arguments are not on point. It is unclear to the Examiner if applicant is arguing the restriction of the species or enablement. It appears to the Examiner to be a discussion on enablement but doesn't specifically traverse the species. Regardless, even if all species where enabled each species must be evaluated for written description, prior art and 112 2nd issues and as stated in the restriction requirement the species are patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph; therefore,

creating undue burden on part of the Examiner. The requirement is still deemed proper and is therefore, maintained. Currently, claims 1-30 are pending. Claims 2, 5-14, 17-21, 23 and 24 are withdrawn as being directed to a non-elected invention. Claim 1, 3, 4, 15, 16, 22 and 25-30 are under examination.

Withdrawn Rejections

All rejections of claims not reiterated herein, have been withdrawn.

Drawings

3. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings submitted 04/25/08 are not labeled in the top margin as Replacement Sheet. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

Replacement Drawing Sheets

Drawing changes must be made by presenting replacement sheets which incorporate the desired changes and which comply with 37 CFR 1.84. An explanation of the changes made must be presented either in the drawing amendments section, or remarks, section of the amendment paper. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). A replacement sheet must include all of the figures appearing on the immediate prior version of the sheet, even if only one

figure is being amended. The figure or figure number of the amended drawing(s) must not be labeled as "amended." If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and within the top margin.

Annotated Drawing Sheets

A marked-up copy of any amended drawing figure, including annotations indicating the changes made, may be submitted or required by the examiner. The annotated drawing sheet(s) must be clearly labeled as "Annotated Sheet" and must be presented in the amendment or remarks section that explains the change(s) to the drawings.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.

If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability.

Specification

4. The disclosure is objected to because of the following informalities: Figure 1 discloses "Pro-Hepcidin(aa25-94)". This should be –Pro-Hepcidin(aa25-84)--. If applicant corrects the drawing, applicant is reminded that each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 3, 4, 15, 16, 22 and 25-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for tissue samples of liver and kidney and a urine sample, does not reasonably provide enablement of blood samples. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. The factors that must be considered in determining undue experimentation are set forth in *In re W*ands USPTQ2d 14000. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The instant claims are directed to a method of detecting hepcidin and a method for diagnosing a condition of a disease characterized by non-physiological levels of hepcidin, comprising obtaining a tissue or fluid sample from a subject; contacting the sample with an antibody or fragment thereof that specifically binds to one or more

carboxy terminal epitopes of SEQ ID NO: 2 and quantifying hepcidin level in the sample; wherein the non-physiological level of hepcidin is indicative of the disease.

The specification fails to teach obtaining blood samples from a subject and utilizing an antibody which specifically binds to one or more carboxy terminal epitopes of SEQ ID NO: 2 and quantifying hepcidin in the sample and diagnosing a condition of a disease. The specification on pages 6-9 disclose obtaining kidney and urine samples from a subject and detecting hepcidin with the antibody EG(1) - HepC which specifically binds the carboxy terminal epitope of SEQ ID NO: 2. Also, Figure 2 shows that this antibody is not reactive in human serum (blood sample). Page 7 discloses that the EG(1) - HepC antibody is reactive with liver and urine sample. Page 70 also discloses liver and kidney samples. Page 55 of the specification specifically teaches that C-terminal antibody EG(1)-HepC was reactive in dot blot, Western blot, immunohitochemistry and immunofluorescence experiments (Figures 1-4) (note that Figures 1-4 only teach the samples are kidney and urine samples), no immunoreactivity could be obtained in ELISA. The compact folding pattern of hepcidin and its tertiary structure in the blood may account for the inability of the EG(1) - HepC antibody to identify circulating hepcidin. Thus, it appears that the disclosure is teaching that the EG(1) - HepC antibody does not detect hepcidin in blood, serum or plasma. Also, Swinkels et al (Clinical Chemistry 52, No. 6, 2006, pages 950-968) teaches that for serum samples only the measurement of prohepcidin is possible, by a commercially available ELISA that uses antibodies directed against amino acid residues 28-47 (N-terminal)(p. 961 2nd col). The specification does not show or teach samples such as

plasma, serum, or blood. that can or could be used in methods of diagnosing as recited nor does the specification teach or show that antibodies which specifically bind to the carboxy terminal epitopes of SEQ ID NO: 2 can detect hepcidin in these samples and as shown above the specification actually teaches that it does not work in samples of blood, serum or plasma. Further, antibodies which specifically bind to the carboxy terminal epitope of hepcidin are not well known in the art. There are no working examples in the specification directed to serum, plasma or blood. The examples of the specification are limited to kidney tissue, liver tissue and urine. Thus, one of skill in the art cannot practice the invention without undue experimentation because of the lack of predictability that these fluids contain hepcidin and further that if it were to contain hepcidin that the hepcidin would be reactive with the recited antibody.

7. Claims 1, 3, 4, 15, 16, 22, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for diagnosing hereditary hemochromatosis, chronic renal insufficiency and renal anemia, does not reasonably provide enablement for diagnosing any and all diseases or diagnosing conditions of diseases as recited such as any an all liver diseases, renal diseases, inflammations, infections, immunologic diseases and tumors as broadly recited. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. The factors that must be considered in determining

undue experimentation are set forth in *In re Wands* USPTQ2d 14000. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The instant claims are directed to a method for diagnosing a condition of a disease characterized by non-physiological levels of hepcidin, comprising obtaining a kidney, liver, blood or urine sample from a subject; contacting the sample with an antibody or fragment thereof that specifically binds to one or more carboxy terminal epitopes of SEQ ID NO: 2 and quantifying hepcidin level in the sample; wherein the non-physiological level of hepcidin is indicative of the disease.

The specification fails to teach diagnosing any and all diseases or diagnosing conditions of diseases as recited using the instantly recited methods. The specification on page 10 provides a laundry list of conditions and discloses that nonphysiological amounts of hepcidin are associated with these conditions. However, the specification does not provide guidance or evidence on how it is associated. There are no tables or graphs showing a positive correlation or a positive diagnosis of a condition of a disease (i.e. quantifying a level of hepcidin from any subject and positively diagnosing the subject as having a tumor). The specification on page 49, line 21- page 50 line 28 discloses the pro-hepcidin levels in hereditary hemochromatosis, chronic renal insufficiency and renal anemia as compared to healthy control groups and shows a

correlation of these levels with the disease as compared to the healthy control groups. Swinkels et al (Clinical Chemistry 52:6 pages 950-968, 2006) teaches that it is not well known of assays for detection and determining the levels of hepcidin. Swinkels teaches that detection and quantification in plasma or urine have not been widely available, and the development of reagents has been hampered by technical difficulties (p. 961, 2nd col). Swinkels also teaches that levels of hepcidin correlate with Hereditary Hemochromatosis and does not teach that it correlates with any and all diseases or disease conditions as recited. Further, there is no evidence such as graphs or statistical values which provide a correlation of hepcidin levels compared to standards or controls other than those discussed above. The only examples in the specification correlating levels of hepcidin with disease are directed to hepcidin levels in hereditary hemochromatosis, chronic renal insufficiency and renal anemia. Further, as indicated above the detection of levels of hepcidin and correlation of levels with disease is not well known in the art. At best the quantification of hepcidin as compared to controls can only be used for diagnosis of hereditary hemochromatosis, chronic renal insufficiency and renal anemia. Therefore, such is not seen as sufficient to support any and all diseases or conditions of diseases as recited and as set forth below it is unclear if the diagnosing is for a condition of a disease or detecting a disease. Further, it is unclear how one would differentiate between a condition of a disease and a disease in order to provide a positive diagnosis of the disease. Thus, one skilled in the art cannot practice the claimed invention without undue experimentation because of the low level of predictability and because if hepcidin is not known to be correlated with any and all

diseases or conditions of disease one cannot positively diagnose the disease without undue experimentation.

8. Claims 27-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting hepcidin by conducting Western blot, immunohistochemistry and immunofluorescence experiments, does not reasonably provide enablement for an any and all assays particularly an ELISA assay. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims are directed to method of detecting hepcidin comprising obtaining a kidney sample, liver sample, a blood sample or a urine sample from a subject and contacting the sample with an antibody or fragment thereof that specifically binds to one or more carboxy terminal epitopes of SEQ IN NO: 2.

The specification fails to teach utilizing any and all assays to determine hepcidin in a sample. Figure 2 of the specification shows that the antibody EG(1)-HepC is not reactive in human serum. Page 55 of the specification specifically teaches that this C-terminal antibody was reactive in dot blot, Western blot, immunohistochemistry and immunofluorescence experiments (Figures 1-4) and that no immunoreactivity could be obtained by ELISA. Thus, it appears that the disclosure is teaching that EG(1)-HepC antibody does not detect hepcidin in ELISA experiments. Also, Swinkels et al (Clinical Chemistry 52, No. 6, 2006, pages 950-968) teaches that for serum samples only the measurement of prohepcidin is possible, by a commercially available ELISA that uses

antibodies directed against amino acid residues 28-47 (N-terminal)(p. 961 2nd col). The specification does not show or teach assays such as ELISA that can or could be used in methods as recited nor does the specification teach or show that antibodies which specifically bind to the carboxy terminal epitopes of SEQ ID NO: 2 can in ELISA assays to detect hepcidin and as shown above the specification actually teaches that this antibody does not work in ELISA assays to detect hepcidin. Further, antibodies which specifically bind to the carboxy terminal epitope of hepcidin are not well known in the art. There are no working examples in the specification directed to an ELISA assay. The examples of the specification are limited to Western blot, immunohistochemistry and immunofluorescence experiments. Thus, one of skill in the art cannot practice the invention without undue experimentation because of the lack of predictability that these antibodies can be used in ELISA assays to detect hepcidin in biological samples and further that if these samples were to contain hepcidin that the hepcidin would be reactive with the recited antibody.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 3, 4, 15, 16, 22 and 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it is unclear if applicant is diagnosing a condition of a disease or if applicant is detecting a disease. The preamble of the claim

recites a method for diagnosing a condition of a disease whereas the body of the claim recites the non-physiological level of hepcidin is indicative of the disease.

Claim 1, line 12 the recitation "the disease" is vague and indefinite because it is unclear what disease applicant is referring to. Further, there is insufficient antecedent basis for this limitation.

Claim 27 is vague and indefinite because the preamble of the claim does not correlate with the body of the claim. The preamble of the claim recites a method of detecting hepcidin. However, the body of the claim does not positively recite a step of detection. Method claims should clearly set forth the various method steps in a positive, sequential manner using active tense verbs such as mixing, reacting, and detecting. Method claims should also clearly state each component used in the method and the relationship of the various components, and should not be a mere cataloging of parts. The claims should also conclude with a step relating the method result to the purpose of the method, preferably to the purpose as also set forth in the preamble of the claims.

Response to Arguments

11. Applicant's arguments filed 04/25/08 have been fully considered but they are not persuasive.

112 first paragraph enablement

Applicant argues that the detection of hepcidin in blood samples by antibodies against the carboxy-terminus of SEQ ID No: 2 is enabled. Applicant directs the

Examiner's attention to paragraph 115 of application US 20070092916 which states as follows:

> [a]lthough the C-terminal antibody EG(1)-HepC reveled specific results in dot Blot, western blot, immunohistochemistry and immunofluorescence experiments (Figs 1-5), it did not work in ELISA. The compact folding pattern of hepcidin and Its tertiary structure in the blood may account for the inability of the EG(1)HepC antibody to identify circulating hepcidin.

Applicant argues that paragraph 115 is recited under a subheading "Detection of Hepcidin Propeptide in Human Plasma". Applicant states that this quotation is devoted to the detection of hepcidin in blood. Applicant states that the recited quote explicitly states that the antibody to the carboxy-terminus of SEQ ID NO: 2 detects hepcidin in "in dot blot, Western blot, immunohitochemistry and immunofluorescence experiments". Applicant states that the instant disclosure enables one of skill in the art to detect hepcidin in blood using antibodies to carboxy-terminus of hepcidin disclosed in the instant application. These arguments are not found persuasive because even though paragraph 115 is under the subheading "Detection of Hepcidin Propeptide in Human Plasma" not all the assays under this heading were performed on blood, in fact the disclosure makes clear that figures 1-5 were performed on liver and kidney samples (see figures 1-5 and page 2 of US 20070092916). Further, in paragraph 115 the EG(1)-HepC antibody did not work in ELISA and the only antibody that did was an N-terminal hepcidin antibody. Thus, paragraph 115 would appear to support the Examiner's enablement rejection.

Applicant argues that the specification does provide enablement for diagnosing any and all disease conditions. Applicant argues that the meaning of the term

"indicative" as used in claim 1 is consistent with Steadman's Medical dictionary, 22nd Ed. (applicant directs the Examiner's attention to Exhibit A) which defines "indication" as "suggestion or pointer". Applicant states that accordingly, the detection of the abnormal hepcidin level does not need to conclusively prove that the patient has certain disease or condition, but rather may serve as an additional criterion for diagnostics of that disease. This is not found persuasive because (1) no such Exhibit A could be found by the Examiner and (2) the instantly recited claims are not directed to the "indication" of a disease condition but rather recite "a method for diagnosing a condition of a disease" and a diagnosis would require a definitive yes of the condition of the disease. Applicant also argues that it is a normal diagnostic practice that the results of several different tests are taken together to conclusively prove whether a patient has the disease in question and accordingly, if it is known that certain disease or condition is characterized by abnormal hepcidin levels, a person of ordinary skill in the art would consider the abnormal hepcidin level in diagnosing a disease, such as recited in claim 1. This is not found persuasive because the instantly recited claims are not for diagnosing a disease but rather appear to be a method of diagnosing a disease condition. Also, there is no guidance or example provided in the specification of combining the levels of hepcidin with any other parameters to positively diagnose a condition of a disease.

Applicant argues that at the time of filing, it was well established fact that hepcidin is a major regulator of iron homeostasis, and that the diseases recited in the claims are characterized by and/or result from abnormal iron levels. This is not found persuasive because claim 1 does not recite disease but rather recites conditions of a disease.

Applicant further argues that in view of the predictability in the art and high level of ordinary skill, extensive guidance and direction are not needed. This is not found persuasive because there would not be a level of high predictability as stated by Applicant because there are no examples or evidence providing a correlation of hepcidin levels to conditions of disease and as taught by Swinkels et al (supra) (Clinical Chemistry 52:6 pages 950-968, 2006) teaches that it is not well known of assays for detection and determining the levels of hepcidin. Swinkels teaches that detection and quantification in plasma or urine have not been widely available, and the development of reagents has been hampered by technical difficulties (p. 961, 2nd col). Swinkels also teaches that levels of hepcidin correlate with Hereditary Hemochromatosis and does not teach that it correlates with any and all diseases or conditions of diseases as recited. Further, there is no evidence such as graphs or statistical values which provide a correlation of hepcidin levels compared to standards or controls. Thus, the level of predictability for diagnosing a condition of a disease in a subject would not be high.

Applicant directs the Examiner's attention to Table 1 of the Remarks section (filed 04/25/08) which lists multiple articles establishing connection between abnormal hepcidin levels and at least some of the diseases recited in the claims, either directly or through the knowledge in the art that these diseases are characterized by abnormal iron metalbolism and that hepcidin is a major regulator of iron homeostais, and is regulated by iron. This is not found persuasive because as stated above the claims are directed to a method of diagnosing a condition of a disease and do not recite diseases. With respect to the argument that the multiple articles provide a connection to diseases this

is not found persuasive because of reasons stated above and further the articles do not provide for the determination of levels of hepcidin or for a direct correlation of these levels for the positive diagnosis of a condition of a disease.

Conclusion

12. No claims are allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Gary W. Counts/
Examiner, Art Unit 1641

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

12/5/2008